4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0012]

Determination of Regulatory Review Period for Purposes of Patent Extension; Rimadyl

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Rimadyl and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brian J. Malkin,

Office of Health Affairs (HFY-20),

Food and Drug Administration,

5600 Fishers Lane,

Rockville, MD 20857,

301-827-6620.

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SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product Rimadyl (carprofen). Rimadyl is indicated for the relief of pain and inflammation in dogs. Rimadyl was shown to be clinically effective for the relief of signs associated with osteoarthritis in dogs. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Rimadyl (U.S. Patent No. 4,264,500) from Pfizer Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 22, 1997, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of Rimadyl represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Rimadyl is 6,572 days. Of this time, 5,910 days occurred during the testing phase of the regulatory review period, 662 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360b(j)) became effective: October 30, 1978. The applicant claims August 23, 1979, as the date the investigational new animal drug application (INAD) became effective. However, FDA records

indicate that the date of FDA's letter assigning a number to the INAD was October 30, 1978, which is considered to be the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act: January 3, 1995. The applicant claims December 29, 1994, as the date the new animal drug application (NADA) for Rimadyl (NADA 141-053) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to NADA 141-053 was January 3, 1995, which is considered to be the initially submitted date for NADA 141-053.

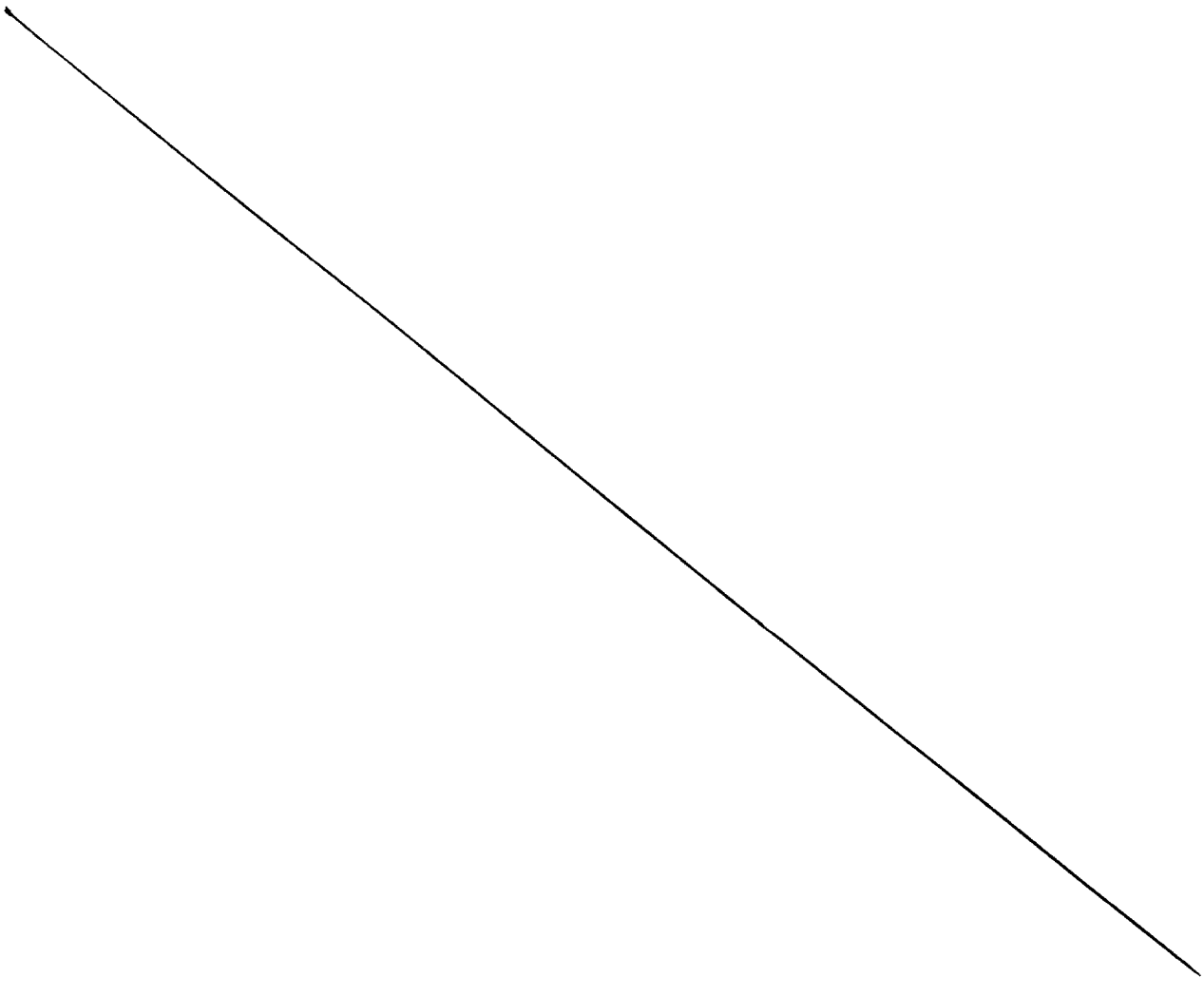
3. The date the application was approved: October 25, 1996. FDA has verified the applicant's claim that NADA 141-053 was approved on October 25, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,095 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER), submit to the Dockets Management Branch (address above) written comments and ask for a

redetermination. Furthermore, any interested person may petition FDA, on or before (insert date 180 days after date of publication in the FEDERAL REGISTER), for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket



number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/28/98
September 28, 1998.

Thomas J. McGinnis

Thomas J. McGinnis, ~~R.Ph~~ BJ Bodo 10-5-98

Deputy Associate Commissioner

For Health Affairs BJ Bodo 10-5-98

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